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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,057	09/07/2004	Pierre Roy	079777-0564 (EGS-005)	8466
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FOLEY & LARDNER LLP			EXAMINER	
111 HUNTINGTON AVENUE			KOHARSKI, CHRISTOPHER	
26TH FLOOR				
BOSTON, MA 02199-7610			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/507,057	ROY ET AL.
	Examiner	Art Unit
	CHRISTOPHER D. KOHARSKI	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 May 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-23 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/16/2008 has been entered.

Response to Amendment

Examiner acknowledges the reply filed 5/16/2008 in which claims 1, 10, 12, 18-20 were amended and new claims 22-23 were added. Currently claims 1-23 are pending for examination in this application.

Claim Objections

Claim 18 is objected to because of the following informalities: The steps of the method disclose steps with the same reference numeral "(i)". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 13-14, the claim element (weakened area) is no longer present in the claim, and thus the further references to the

notch, location, and use lack antecedent basis in the claim. For the purposes of examination, the Examiner will treat the notch weakened area and separate limitation included in the above referenced claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 11-12, and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Mericle (USPN4,214,586). Mericle discloses an anastomotic coupling device.

Regarding claims 1-6, 8, 11-12, and 15-16, Mericle discloses a connection assembly (Figures 1-3, and 7) for transferring a fluid, particularly a fluid containing active products, from a reservoir to a medical delivery device comprising: a first (14) connection element associated with the reservoir and comprising first retaining means; a second connection (16) element associated with the medical delivery device and comprising second retaining means capable of cooperating with the first retaining means to form an irreversible connection between the two elements (Figures 4, 7); wherein the first and second retaining means are arranged such that they cooperate with each other by clipping (18, 15) during a single translation movement of one connection element with respect to the other to make the connection irreversible; and at least one of the first and second connection element is reversibly connectable to

standard connectors (ends of 14, 15, Figures 1 and 7) allowing fluid transfer therethrough before an irreversible connection is made with the other element, wherein either the first or second retaining means comprises at least one elastically deformable tab (18, 24) and the other retaining means comprises at least one lip (14, 15) capable of cooperating with the tab, wherein either the first or second retaining means comprises two tabs (Figure 6) located on opposite sides of the first or second connection element.

Claim Rejections - 35 USC § 102

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Matkovich (USPN5,810,398). Matkovich discloses a fluid delivery systems and methods and assemblies for making connections.

Regarding claim 18, Matkovich discloses a method (Figure 14) for forming a connection for transferring a fluid, particularly a fluid (within 600) containing active products, between a reservoir (600) and a medical delivery device (20) comprising the steps of: (ia)reversibly connecting at least one of a first connection element associated with the reservoir (via tube 10) and a second connection element associated with the medical delivery device (via tube 20) to respective standard connectors allowing fluid transfer therethrough before an irreversible connection is made with the other connecting element (100, 200); (ib) translating the first connection element having a first retaining means (158) relative to the second connection element having a second retaining means (end 230); (ii) irreversibly connecting together the translated first and second connection elements through cooperation of the first and second retaining means; and (iii) transferring a fluid between the reservoir and the medical delivery

device through the irreversibly connected first and second connection elements (Figures 1-14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9 and 17 are rejected under 35 U.S.C 103(a) as being unpatentable over Mericle (USPN4,214,586) in view of Erskine et al. (USPN5,820,614). Mericle meets the claim limitations as described above except for the non-return means.

However, Erskine et al. teaches a connection for medical access devices.

Regarding claims 9 and 17, Erskine et al. teaches medical access connector (20, 30) for connection between a reservoir (14) and a delivery member (40) (Figures 2-2a) with an internal non-return means (52, 57) which prevents fluid return through the connector.

At the time of the invention, it would have been obvious to add the valve flow control means in order to prevent backflow through the assembly or provide for single unidirectional flow through the assembly. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Erskine et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 10, 13-14, and 19-23 are rejected under 35 U.S.C 103(a) as being unpatentable over Mericle (USPN4,214,586) or Matkovich (USPN5,810,398) in view of Folden (USPN5,221,267). Mericle or Matkovich meets the claim limitations as described above except for the weakened area that can be broken by shear force.

However, Folden teaches a breakable tubing coupling.

Regarding claims 10, 13-14, and 19-23, Folden teaches a connection device between a reservoir (29) and medical device (22, 24) that comprises a weakened area comprising a continuous notch (38) located behind an annular ring (50) that is breakable in response to shear force (Figure 3).

At the time of the invention, it would have been obvious to add the weakened section of Folden to the device of Mericle or Matkovich in order to allow for a quick disconnect of the connection without a knife or scissors. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Folden (cols 3-4).

Claim Rejections - 35 USC § 103

Claim 7 is rejected under 35 U.S.C 103(a) as being unpatentable over Mericle (USPN4,214,586).

Regarding claim 7, Mericle discloses the claimed invention except for the specific connection tube taper.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Mericle with the taper as claimed since it is well known to vary the size and shape of tubing connector depending on the fluid and area of the body to be treated, and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests the addition of both connection members in conjunction with the weakened area, with further clarification of the structure of the attachments as shown in Figure 9.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 9/10/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763